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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/961,414	09/25/2001	Fumiyasu Hirai	12218/1	6930

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EXAMINER	
FORD, VANESSA L	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 03/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/961,414	HIRAI ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2004* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4 and 6-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4 and 6-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

FINAL ACTION

1. This Office Action is responsive to Applicant's amendment and response filed January 5, 2004. Claim 4 has been amended. Claims 1-3 and 5 have been cancelled. Claims 8-10 have been added.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Objection Withdrawn

3. In view of Applicant's amendment the objection of claim 4, page 2, paragraph 2 is with drawn.

Rejections Maintained

4. The rejection under 35 U.S.C. 102(b) as anticipated by Fukuyama is maintained for claims 4, 6-7 and newly added claims 8-9 the reasons set forth on pages 3-4 paragraph 4 of the previous Office Action.

The rejection was on the grounds that Fukuyama et al teach a method of removing superantigens which include enterotoxins staphylococcal enterotoxin A (SEA), staphylococcal enterotoxin B (SEB) and staphylococcal enterotoxin C (SEC) from body fluids (see the Abstract). Fukuyama et al teach that the body fluids used in the invention can be blood, plasma or serum (page 2, lines 49-51). Fukuyama et al teach that removal of SEA, SEB and SEC from rabbit plasma (pages 5-6). Fukuyama et al teach the use of water-insoluble materials, which include porous insoluble materials that can be used in the invention (page 5). Fukuyama et al teach the use of amines in the invention such as sec-octyl-amine, diethyleneiamine, triethylenatetramine and many others (page 4). Therefore, Fukuyama et al teach adsorbents comprising a compound with a log P in which P represents a partition coefficient in an octanol-water system value of not less than 2.50 as immobilized on a water-insoluble carrier since the specification at page 7 lists amines as a preferred group of compounds having P values

not smaller than 2.50. The claim limitation "wherein said water-insoluble porous carrier has a molecular weight of exclusion limit 5,000 to 600,000 for globular protein" would be inherent in the prior art. The method of Fukuyama et al, et al appears to be the same as the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that Fukuyama does not anticipate the claimed invention because Fukuyama does not teach a compound that has a log P value of not less than 3.00.

Applicant's arguments filed January 5, 2004 have been fully considered but they are not persuasive. Fukuyama teaches a method for the elimination or detoxification of superantigens from body fluids using adsorbents comprising compounds such as isocyanates, alcohols, carboxylic acids and derivatives and amines (page 4). It should be noted that adsorbents comprising compounds such as isocyanates, alcohols, carboxylic acids and derivatives and amines, which have log P values not smaller than 2.50 (i.e. 2.50 or more) of the prior art are the same as the adsorbents used in the claimed method (see page 7 of the instant specification). Therefore, the adsorbents comprising the compounds recited in the prior art meet the claim limitation "... a compound with a log P value, in which P represents a partition coefficient in an octanol-water system of not less than 3.00 as immobilized on a water-insoluble carrier". Applicant has provided no side-by-side comparison to show that the adsorbents comprising the compounds with a log P value of not less than 3.00 used in the method

of the prior art are not the same as the adsorbents used in the claimed method.

Therefore, Fukuyama anticipates the claimed invention.

5. The rejection of claims 4, 6-7 and newly added claims 8-10 under 35 U.S.C. 103(a) as unpatentable over Nagaki et al in view of Hirai et al is maintained for the reasons set forth on pages 5-7, paragraph 5 of the previous Office Action.

The rejection was on the grounds that Nagaki et al teach a method for adsorptive removal of enterotoxin A from plasma of rats using various adsorbents (see the Title and the Abstract). Nagaki et al disclose a study that evaluates the capacity of various adsorbents to bind enterotoxin A and directly remove the toxin from the circulation (page 354, 2nd column). Nagaki et al teach that the direct removal of enterotoxins from the circulation may be of potential therapeutic value in preventing the consequences of staphylococcal septicemia (page 354, 2nd column).

Nagaki et al do not teach the use of an adsorbent comprising a compound with a log P in which P represents a partition coefficient in an octanol-water system value of not less than 2.50 as immobilized on a water-insoluble carrier.

Hirai et al teach an adsorbent comprising a compound which has a log P value of at least 2.50 wherein P is a partition coefficient in an octanol-water system and which is immobilized on a water –insoluble carrier used to eliminate toxins from body fluids by adsorption (see the Abstract). Hirai et al teach that the water-insoluble carrier is a porous carrier which has an exclusion limit for globular protein of 10,000 to 600,000 (page 5, paragraphs 0033 and 0034).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to add the adsorbent as taught by Hirai et al to the adsorbents used in the method for adsorptive removal of enterotoxin A from plasma of Nagaki et al because Hirai et al teach that the adsorbents comprising compound which has a log P value of at least 2.50 can used in alone or combination with compounds that have a log P value of less than 2.50 to remove toxins (page 4, paragraph 0027). It would be expected barring evidence to the contrary that the addition of the adsorbents as taught by Hirai et al to the adsorbents used in a method of removing enterotoxins from body fluids of Nagaki et al can be effective in removing enterotoxins from body fluids because Hirai et al have demonstrated that the adsorbents comprising compound which has a log P value of at least 2.50 can be used to remove toxins (i.e. toxic shock syndrome toxin –1 (TSST-1)) which is a toxin released by *Staphylococcus aureus* that is structurally closely related to enterotoxins (Nagaki et al, page 354, 1st column). Additionally, the exclusion limit as described by Hirai et al for the removal of TSST-1 is within the range of the exclusion limit for the removal of the claimed staphylococcal enterotoxins.

Applicant urges that there is no motivation to combine the teachings of Nagaki et al with the teachings of Hirai et al. Applicant urges that there is no reasonable expectation that the combination of references would be successful in arriving at the claimed invention. Applicant urges that Nagaki et al merely describes that enterotoxins and TSST-1 are structurally related and does not teach or suggest that TSST-1 and enterotoxins have the similar adsorption properties.

Applicant's arguments filed January 5, 2004 have been fully considered but they are not persuasive. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Nagaki et al teach a method of removing enterotoxins using adsorbents and Hirai et al teach that TSST-1 can be removed using compounds that have a P value of at least 2.50, most preferably 2.80 or more and more preferably 3.0 or more (page 3). It would be obvious to use the compounds as taught by Hirai et al in the method of removing enterotoxins as taught by Nagaki et al because Hirai et al teach that adsorbents comprising compounds such as isocyanates, amines, alcohols, halides, aldehydes, hydrazides, carboxylic acids and derivatives thereof, thiols and unsaturated

hydrocarbons, silanes (which have log P values of not less than 3.00) can be used to remove TSST-1 which is structurally similar to enterotoxins (page 4). Hirai et al specifically teach that amines such as hexadecylamine can be used in the method of removing TSST-1 (page 4). It should be noted that the adsorbent comprising compounds with log P values of not less than 3.00 as immobilized on a water-insoluble carrier used for the removal of TSST-1 as taught by Hirai et al are the same as the adsorbents used in the claimed method of removing enterotoxins (see page 7 of the instant specification). Therefore, one of skill in the art would reasonably conclude that TSST-1 (an exotoxin) and enterotoxins have similar adsorbent properties and TSST-1 as well as enterotoxins can be removed using an adsorbent comprising a compound with a log P value of not less than 3.00 as immobilized on a water-insoluble carrier with a reasonable expectation of success. Therefore, there is nothing on the record to teach or suggest that the combination of references do not teach the claimed method.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Status of Claims

7. No claims allowed.

8. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Vanessa L. Ford
Biotechnology Patent Examiner
March 15, 2004

MARK NAVARRO
PRIMARY EXAMINER